

## REMARKS

This Amendment is respectfully submitted in response to the Office Action rendered October 21, 2003. It is timely submitted in view of the Petition for Extension of Time submitted concurrently herewith.

The claims have been amended as follows: Claim 16 has been amended to remove the reference to the "prevention of acne" in order to clarify the embodiments of applicants' invention to which the claims herein are directed. Claims 16, 19 and 22 have also been amended to remove the reference to "non-fractionated" soy product and to insert reference to "non-denatured" soy product. Basis for this amendment may be found in the Specification at page 7, l. 10-12.

The Office Action of October 21, 2003 rejected claims 16, 19 and 22 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirements. The basis for this rejection is given that "Claims 16, 19 and 22 as amended introduce new matter as they use the phrase 'non-fractionated soy product'" [Office Action, p. 2] which is alleged not to be present in the specification as filed. Applicants respectfully request reconsideration of this rejection in view of the foregoing amendments to the claims and ensuing discussion.

Applicants have removed the reference to "non-fractionated soy product" and respectfully direct the Patent Office's attention to the Specification at page 7, lines 1-14. The inventors have defined the term "soy product" to mean "a substance derived from the soybean, containing the ingredients naturally found in soybeans, at the relative concentrations as found in the beans." [Specification, p. 7, l. 3-6]. Thus, the term "soy product" relates to substances derived from soybeans that have not been concentrated in distinction from substances derived from soybeans that **have** been concentrated. Applicants respectfully request reconsideration of this rejection in light of the amended claims.

The Office Action of October 21, 2003 further rejected claim 16 under 35 U.S.C. 112, first paragraph "because the specification, while being enabling for the method of treating acne, does not reasonably provide enablement for the method of preventing acne." [Office Action, p. 3]. Applicants respectfully request reconsideration of this rejection in view of the foregoing amendments to the claims and the ensuing discussion.

Applicants respectfully point out that the claim 16 has been amended to remove reference to "prevention of acne" in order to clarify the method of their invention to which it pertains. Applicants respectfully request reconsideration of this rejection in light of the amendment.

Claim 22 was rejected under 35 U.S.C. 112, first paragraph "because the specification, while being enabling for the method of treating sunburn, does not reasonably provide enablement for the method of preventing sunburn." [Office Action, p. 7] Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

Applicants respectfully direct the attention of the Patent and Trademark Office to the Specification at page 25, l. 16 through page 26, l. 5, Example 8 of the Specification. In this example, an individual applied a composition according to the invention to the right half of his face once daily for eight weeks **prior to** exposure to the sun. He was exposed to the sun and did not use sunscreen on either side of his face. By the second and third day after sun exposure, the left half of his face became red, painful and scaly. However, unexpectedly, the right half of his face was not red, painful or scaly. Furthermore, Figures 5 and 6 of the Specification show the two sides of the individual's face, demonstrating that the compositions of the invention, when applied topically prior to sun exposure, **prevent** sun-induced damage to the skin. Applicants respectfully submit that this example provides strong evidence that applying the soymilk compositions of applicants' invention to the skin will assist in preventing damage caused by sun exposure. Applicants respectfully request reconsideration of the rejection under 35 U.S.C. 112, first paragraph in view of the demonstration set forth in the Specification relating to prevention of sun-induced skin damage.

Claims 15, 17, 18, 20 and 21 were rejected as being anticipated by Voegeli et al. The basis for this rejection was as follows:

Voegeli et al. teach cosmetic and dermatological compositions comprising powdered protein fraction from Leguminosae seeds, such as soybeans and lima beans, and a water-soluble preservative, such as methylparaben...The soybean protein fraction exhibits trypsin-inhibiting activity and provides hydrating, itch soothing, anti-inflammatory and elasticity increasing effects...The methods claimed in the instant claims are inherent in the reference because the reference explicitly teaches the claimed method step, i.e., applying to the skin a topical skin care composition comprising a non-denatured soy product and a stabilizer. [Office Action, p. 11]

Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

Applicants respectfully submit that the Voegeli et al. patent describes a specific fraction from Leguminosae seeds made utilizing the following procedure:

The protein fractions of the present invention can be obtained from the cited seeds of leguminous plants by grinding the dried seeds, extracting the obtained flour with an organic solvent or a mixture of solvents, drying and extracting the flour defatted in such a way with water or an aqueous electrolyte solution at a pH of 2 to 10, preferably at pH 5 to 6, adjusting the extract to pH 5 to 7, concentrating under vacuum, clarifying filtering or centrifuging the concentrate under addition of a filter aid such as keiselguhr, separating the proteins therefrom either by salt precipitation...or by precipitation with an organic, watermiscible solvent such as ethanol in a concentration of 60 to 90% v/v, collecting by filtration or centrifugation and finally either drying directly in the vacuum or first removing salts by dialysis, gel filtration or ultrafiltration and then lyophilizing...[Voegeli, et al., col. 2, l. 49-65]

Applicants respectfully point out that the claimed compositions of their inventions are defined as having ingredient concentrations as close to the naturally-occurring soy bean as possible:

What is meant by "soy product" is a substance derived from the soybean, **containing the ingredients naturally found in soybeans, at the relative concentrations as found in the beans.** In one embodiment, the soy product is a non-denatured soy product. "Denaturation" is defined...as "the change in the physical and the physiological properties of a protein, that are brought about by heat, X-rays or chemicals..."[Specification, p. 7, l. 3-8] (emphasis added)

The concentrations of ingredients in naturally-occurring beans are quite dilute, as opposed to the treated, extracted and concentrated fractions set forth in Voegeli et al. Nowhere in Voegeli, et al. is there a suggestion or description of these claimed compositions of applicants' invention. Rather, Voegeli et al. requires very **extensive** treatment, extraction and concentration steps that obtain very specific fractions of the leguminous seeds described therein. These concentrated fractions are not the substances containing the ingredients naturally found in soybeans at the relative concentrations as found in the beans, as set forth in the claims. Therefore, applicants respectfully submit that Voegeli et al. does not teach the compositions and methods of applicants' claimed invention. Thus, applicants respectfully request reconsideration of the rejection set forth in the Office Action of October 21, 2003 in view of Voegeli, et al.

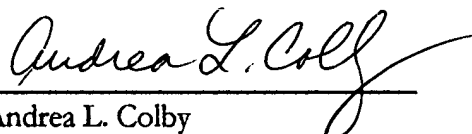
Previously-submitted Information Disclosure Statements are currently being reviewed and update and, if appropriate, additional patents and publications will be submitted under separate cover for the consideration of the Patent and Trademark Office.

On the basis of the foregoing amendments to the claims and discussion, applicants respectfully request reconsideration of the rejections set forth in the Office Action of October 21, 2003. Consideration of new claims 26-29 is respectfully requested. An early allowance is earnestly solicited.

Authorization of Deposit Account

The Commissioner is hereby authorized to charge any fees or credit any overpayment, to Deposit Account 10-0750. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire prosecution of this application.

Respectfully submitted,



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April 21, 2004

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